212. A composition comprising a fusion protein of claim 132 and a pharmaceutically acceptable carrier.

213. A composition comprising a fusion protein of claim 134 and a pharmaceutically acceptable carrier.

REMARKS

Claims 113-195 are pending in the application. Claims 121, 122, 126, 136-148, 151-195 have been cancelled without prejudice. Claims 113-120, 123, 125, 127-132, 134, 149 and 150 have been amended. New claims 196-213 have been added. Accordingly, claims 113-120, 123-125, 127-135, 149, 150 and 196-213 are pending following entry of the above amendments.

Support for the new claims and claim amendments can be found in the specification and claims as originally filed. Support for new claims 196-198 and 202-204 can be found in the specification at least, for example, at page 57, lines 8-20, at page 60, line 10 through page 61, line 18, and at page 50, line 24 through page 51, line 2. Support for new claims 199-201 can be found in the specification at least, for example, at page 57, lines 8-20, at page 60, line 10 through page 61, line 18, and at page 52, lines 7-11, and at page 72, lines 25-29. Support for new claim 205 can be found in the specification at least, for example, at page 3, lines 29-38. Support for new claims 206-211 can be found in the specification at least, for example, at page 50, lines 24-32. Support for new claims 212-213 can be found in the specification at least, for example, at page 51, lines 3-11. Support for amended claims 113 and 120 can be found in the specification at least, for example, at page 50, lines 24-32. Claims 123, 132, 134, 149 and 150 have been amended to correct the dependency or to make minor editorial changes in view of the foregoing claim amendments. No new matter has been added. For the Examiner's convenience, the claims that will be pending in the application upon entry of the instant Amendment are set forth in Appendix A.

Any amendments to and/or cancellation of the claims is not to be construed as an acquiescence to any of the rejections set forth in the instant Office Action, and was done solely to expedite prosecution of the application. Applicant hereby reserves the right to pursue the subject matter of the claims as originally filed in this or a separate application(s).

Examiner Interview

Applicant gratefully acknowledges the courtesy of a telephonic interview with the Examine and Applicant's attorney Amy E. Mandragouras on January 13, 2000 during which the above amendments were discussed.

Election/Restriction

Pursuant to 35 U.S.C. §121, the Examiner has found that the above-referenced application is directed to two or more independent and distinct inventions. In a telephone conference of July 18, 1999, Applicant's attorneys elected Group I (claims 113-157) for search and examination with traverse. Applicant hereby affirms the election of the Group I invention which encompasses claims 113-157. In view of this affirmation, claims 158-195, directed to non-elected inventions, have been cancelled without prejudice to further prosecution in one or more continuing applications. The newly added claims are believed to be drawn to the elected invention.

Allowable Subject Matter

Applicant gratefully acknowledges the Examiner's indication that SEQ ID NO 764 is not taught or reasonably suggested by the prior art of record, and that claim 124 is allowed, as set forth in the pending Office Action dated July 29, 1999 (Paper No. 26).

The Examiner indicates that the claimed composition of the polypeptide set forth in SEQ ID NO:764 is "being read as isolated and purified from other *H. pylori* antigens",

as "the polypeptide would have to have been significantly purified in order to determine the now recited amino acid sequence SEQ ID NO:764."

Applicant respectfully traverses the above quoted statements by the Examiner as an improper interpretation of claim 124. As written claim 124 is directed to "an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 764." The claim is not limited to a naturally occurring polypeptide being isolated and purified from *H. pylori*, but encompasses polypeptides which are produced by recombinant techniques as well as chemical synthesis (see the specification, for example, at page 55, lines 16 through page 56, line 4, and at page 61, line 19 through page 62, line 8). In fact, the amino acid sequence set forth in SEQ ID NO:764 was obtained following sequencing of the entire *H. pylori* genome using a whole genome random shotgun cloning and sequencing technique155 (see, e.g., Fleischmann *et al.*, July 1995, *Science* 269:496-51), and contains a mutation resulting in a frameshift at position 155. Briefly, a random *H. pylori* DNA fragment library was prepared by random digestion of chromosomal DNA, the random fragments cloned into vectors and sequenced using multiplex DNA sequencing methods, and the sequence information assembled using computer assembly software. Following DNA sequencing, open reading frames were identified and amino acid sequences deduced. As claim 124 encompasses isolated polypeptides derived from *H. pylori* as well as polypeptides produced by recombinant techniques or chemical synthesis, the Examiner's above-quoted statements are an improper interpretation of claim 124 as written. Reconsideration and withdrawal of the these remarks is respectfully requested.

Claim Rejections - 35 U.S.C. §101

The Examiner has rejected claims 113-123, 132-139, 149, 150, 152, 153, 155, and 156 under 35 U.S.C. §101, based on the recitation of the term "recombinant polypeptide." In particular, the Examiner indicates that the word "recombinant" is being read as a process step which can be carried out in nature or in the laboratory and not a state of purity, and states

> recombination takes place in nature and would therefore result in the production of recombinant polypeptides. Akopyanz is cited to show that diversity among

> isolates of Helicobacter pylori, and recombination and expression of polypeptide naturally occurs in nature.

Claims 121, 122, 136-139, 152, 153, 155 and 156 have been cancelled, thus as applied to these claims the rejection is rendered moot. With regard to claims 113-120, 123, 132-135, 149 and 150, Applicant respectfully traverses this rejection, as it does not apply to the claims as amended which are directed to "isolated" polypeptides. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

Claim Rejections – 35 U.S.C. §112, First paragraph

Rejection of Claims 148-157 Under 35 U.S.C. §112, First Paragraph

The Examiner has rejected claims 148-157 under 35 U.S.C. §112, first paragraph, because "the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims." In particular, the Examiner indicates that the phrase "pharmaceutically acceptable carrier" is being read as a component of a composition for administration to an animal which serves or may serve as a host to Helicobacter, and is of the opinion that

> the specification, while being enabling for claims limited compositions comprising SEQ ID No 764 (the elected invention), a method of purifying or synthesizing said SEQ ID NO 764, a method of culturing Helicobacter pylori, recombinantly produced Helicobacter antigen, DNA, vectors, host cells comprising the nucleic acid sequence which encodes SEQ ID No 764, does not reasonably provide enablement for a vaccine or compositions comprising an effective amount of an immunogenic composition.

The Examiner further states that

> [f]rom the specification it is clear that Applicant has identified an antigenic polypeptide which results in an reacting with an antibody and could be easily

produced by methods known in the art of protein chemistry but it is not clear that the polypeptide results in prevention of infection and disease. No art recognized *in vitro* or *in* vivo models are shown in which protection is produced from the instantly claimed invention. It is clear the polypeptide is immunogenic but it is not clear that the composition would result in prevention of infection or disease. No examples containing the missing information are shown.

Claims 148 and 151-157 have been cancelled, thus as applied to these claims the rejection is rendered moot. With regard to amended claims 149 and 150, Applicant respectfully traverses this rejection as follows.

Claims 149 and 150, as amended, are directed to compositions comprising a polypeptide of any one of claims 113, 120, 125 or 196-204 and a pharmaceutically acceptable carrier. Thus, the scope and nature of the invention encompassed by these claims pertains to compositions comprising a polypeptide and a pharmaceutically acceptable carrier.

Applicant respectfully maintains that the specification enables one skilled in the art to make and use the invention commensurate in scope with the claims. Firstly, as cited above, the Office Action clearly admits that the instant specification enables the polypeptide of SEQ ID NO:764 as an immunogenic polypeptide, as well as compositions comprising the polypeptide of SEQ ID NO:764. In addition, Applicant's specification, provides significant guidance for the use of compositions comprising polypeptides of the invention. For example, at pages 56-58, the instant specification discloses the immunization of animals with polypeptides in the presence of an adjuvant in order to generate antibodies, *e.g.*, for diagnostic use. Thus, based on the teachings of the specification, it would not have required undue experimentation for one of skill in the art to make and use the claimed invention without undue experimentation.

For at least the aforementioned reasons, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

Applicant reserves the right without prejudice to pursue claims as amended and/or cancelled directed to immunogenic polypeptides, compositions comprising such polypeptides, and vaccine compositions comprising an effective amount of a polypeptide or immunogenic polypeptide of the invention in this or another application.

Rejection of Claims 113-119, 121-123, 132-139, 150, 153 and 156 Under 35 U.S.C. §112, First Paragraph

The Examiner has rejected claims 113-119, 121-123, 132-139, 150, 153 and 156 under 35 U.S.C. §112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." In particular, the Examiner states

> [t]he recitation of the word "BLASTP" does not evidence original descriptive support in the specification and is therefore considered to be new matter. The phrase "percent sequence identity " also does not evidence original descriptive support in the specification and is therefore considered to be new matter.

Claims 121, 122, 136-139, 153 and 156 have been cancelled, thus as applied to these claims the rejection is rendered moot. Applicant respectfully submits that claim 113, as amended, does not recite the language "BLASTP", thus obviating the rejection as it pertains to this claim. With regard to claim 113 and claims which depend therefrom, Applicant respectfully traverses this rejection as follows.

Claim 113, as amended, is directed to an isolated polypeptide comprising an amino acid sequence that is identical to an amino acid sequence of a naturally occurring *H. pylori* polypeptide which has at least 60% sequence identity with SEQ ID NO:764. As set forth in new claim 205, sequence identity can be determined by the following algorithm:

(1) aligning the amino acid sequence with SEQ ID NO:764 to identify the number of matching positions shared by the amino acid sequence and SEQ ID NO:764,

(2) dividing the number of matching positions by the total number of amino acids in SEQ ID NO:764, and

(3) multiplying the dividend by 100.

With regard to claim 113, as amended, and new claim 205, Applicant maintains that the specification provides sufficient written description of the use of sequence alignment to compare two sequences such that a skilled artisan would recognize that they had invented what is claimed. In particular, at page 3, lines 29-38, the specification

teaches the use of the algorithm (steps (1) through (3) recited in claim 205, as set forth above), to compare two sequences in order to identify matching or "identical" positions shared between the sequences. Applicant submits that the determination of "sequence identity" as the percentage of residues identical between two aligned sequences is well known in the art, and that the algorithm provided at page 3 of the specification and recited in new claim 205 is art-recognized. Moreover, at page 63, lines 3-9 of the specification, Applicant discloses the use of the BLAST algorithm to perform sequence comparisons. As indicated in the specification, the BLAST algorithm provides a probability score for each sequence related to the query sequence. In addition, the BLAST algorithm also provides the percent identity between the aligned sequences, the calculation of which is consistent with the above recited algorithm. Accordingly, Applicant respectfully submits that there is sufficient written description in the instant application to inform a skilled artisan that Applicant was in possession of the claimed invention at the time the application was filed.

In light of the foregoing, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

Rejection of Claims 113-123 and 125-141 Under 35 U.S.C. §112, First Paragraph

The Examiner has also rejected claims 113-123 and 125-141 under 35 U.S.C. §112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Specifically, the Examiner is of the opinion that

> [a]s the instant specification is clearly enabled and provides written descriptive support for SEQ ID No 764, no specific isolated or recombinant polypeptides which share 60%,70%,80%,90%,95%,98% or 99% sequence identity evidence original descriptive support in the instant specification.

The Examiner further argues that

> [c]ompositions comprising specific immunogenic polypeptides which comprise any 5-100 consecutive amino acids are not taught in such a way as to define an

effective amount of immunogenic polypeptide as the administration of SEQ ID NO 764 does not evidence original descriptive support in the instant specification. The claimed immunogenic polypeptides do not consist of SEQ ID No 764 but portions of the SEQ ID are included in a larger immunogenic polypeptide as now claimed. No specific immunogenic polypeptide, which are not immunogenic fragments of the recited SEQ ID No 764, are described. The portions of SEQ ID NO 764 which are used in the formulation of the claimed immunogenic polypeptides need not be immunogen portions of SEQ ID No 764.

Claims 121, 122, 126 and 136-141 have been cancelled, thus as applied to these claims the rejection is rendered moot. With regard to amended claims 113-120, 123, 125, and 127-135, Applicant respectfully traverses the aforementioned rejection.

I. The Specification Provides Sufficient Written Description Of Polypeptides Having At Least 60% Sequence Identity With SEQ ID NO:764

With regard to the Examiner's assertion that isolated polypeptides which share 60-99% sequence identity with SEQ ID NO:764 do not evidence original descriptive support in the specification, Applicant respectfully submits that there is sufficient written description in the instant specification to inform a skilled artisan that Applicant was in possession of the claimed invention at the time of filing, as required by U.S.C. §112, first paragraph (see M.P.E.P. 2163.02).

"Written description may be satisfied through disclosure of relevant identifying characteristics, i.e., structure, other physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. §112, First Paragraph Written Description Requirement.* Moreover, "[a] specification may, within the meaning of 35 U.S.C., § 112, First Paragraph, contain a written description of a broadly written claimed invention without describing all species that claim encompasses." *Utter v. Hiraga*, 845 F.2d 993, 6 USPQ2d 1709 (Fed. Cir. 1988).

For reasons discussed in detail below, the instant specification satisfies this requirement for the claimed invention.

Claim 113, as amended, is directed to an isolated polypeptide comprising an amino acid sequence that is identical to an amino acid sequence of a naturally occurring

H. pylori polypeptide which has at least 60% sequence identity with SEQ ID NO:764. Amended claims 114-119 depend from and further limit claim 113 by specifying that the polypeptide comprises at least 70%, 80%, 90%, 95%, 98% and 99% sequence identity with SEQ ID NO:764, respectively. Amended claims 132 and 133 depend from claim 113.

Claim 120, as amended, is directed to an isolated polypeptide comprising an amino acid sequence that is identical to an amino acid sequence of a naturally occurring *H. pylori* polypeptide, the polypeptide comprising at least 10 amino acids and being encoded by a nucleotide sequence which hybridizes under high stringency conditions to the complement of a nucleotide sequence encoding SEQ ID NO:764. Amended claims 123, 132, and 133 depend from claim 120.

Applicant respectfully submits that the claimed genus of polypeptides having at least 60% sequence identity with SEQ ID NO:764 and polypeptides encoded by a nucleic acid sequence which hybridizes under high stringency conditions to the complement of a nucleotide sequence encoding SEQ ID NO:764 is defined by structural features that are described in the specification, recited in the claims, and commonly possessed by its members. Firstly, the specification teaches the structure, *e.g.*, the amino acid sequence of a polypeptide (SEQ ID NO:764), common to each of the claimed polypeptides. The specification further teaches at, for example, page 50, lines 24 through page 51, line 2, and at page 72, lines 25-31 that the invention includes allelic variations, as well as natural and induced mutants of the polypeptides of the invention. In addition, the instant specification describes in detail how to make the claimed polypeptides (see, for example, pages 58-60 and pages 64-67), how to assay for functional activity, *e.g.*, immunogenecity (see, for example, pages 60-61), and how to use the polypeptides (see, for example, pages 56-58). Thus, the teachings of the instant specification convey that Applicant was in possession of the claimed invention and had a full conception of the scope of the invention at the time the application was filed.

Furthermore, claims 113 and 120, as amended, are drawn to isolated polypeptides which include an amino acid sequence that is identical to a naturally occurring *H. pylori* polypeptide. Applicant teaches that such naturally occurring polypeptides can be identified by determining sequence identity with the amino acid sequence of SEQ ID

NO:764 or by detecting hybridization of the nucleic acid encoding the polypeptide with a complement of the nucleic acid sequence encoding SEQ ID NO:764 under high stringency conditions. In view of the above remarks, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

II. The Specification Provides Sufficient Written Description Of Compositions Comprising Immunogenic Polypeptides Comprising At Least 5 Consecutive Amino Acids

With regard to the Examiner's assertion that immunogenic fragments of the polypeptide of SEQ ID NO:764 do not evidence original descriptive support in the specification, Applicant respectfully submits that there is sufficient written description in the instant specification to inform a skilled artisan that Applicant was in possession of the claimed invention at the time of filing.

Claim 125, as amended, is directed to an isolated polypeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO:764. Amended claims 127-131 depend from and further limit claim 125 by specifying that the isolated polypeptide comprises at least about 12, 16, 20, 50 and 100 consecutive amino acid residues, respectively, of SEQ ID NO:764.

The Examiner has taken the position that compositions comprising specific immunogenic polypeptides are not taught in such a way as to define an effective amount of the immunogenic polypeptide.

Applicant respectfully submits that claim 125, as amended, does not recite the term "immunogenic" and thus as applied to this claim and claims which depend therefrom, the above-quoted rejection is rendered moot.

However, with regard to new claims 202-204 which recite isolated polypeptides comprising at least 10 consecutive amino acid residues of SEQ ID NO:764 and having at least one epitope recognized by a T cell receptor specific for the polypeptide set forth in SEQ ID NO:764; at least one antigenic determinant of the polypeptide set forth in SEQ ID NO:764; or which is immunologically crossreactive with the polypeptide set forth in SEQ ID NO:764, Applicant wishes to make the following remarks of record.

Applicant's specification defines an immunogenic polypeptide as having the ability to induce a T cell response such as stimulation (e.g., proliferation, cytokine secretion). In particular, an immunogenic polypeptide which has the ability to stimulate T cells is defined as comprising at least one T cell epitope which can stimulate a T cell population with the relevant T cell receptor for the epitope (see, for example, the specification at pages 60-61). In addition, an immunogenic polypeptide is described as comprising an antigenic determinant which is specifically recognized by antibodies that recognize that polypeptide (see, for example, the specification at page 57). These functional characteristics of immunogenic polypeptides are recited in new claims 202-204.

Applicant respectfully submits that the common features of the immunogenic fragments of the polypeptide of SEQ ID NO:764 are taught in the specification and recited in the claims. For example, the instant specification describes in detail how to enhance the immunogenecity of the claimed polypeptides (see, for example, pages 57-59), how to identify immunogenic polypeptides *in vitro* based on the ability to induce a T cell response (see, for example, pages 60-61), and how to use the polypeptides, *e.g.*, to generate antibodies (see, for example, pages 56-58). In view of the above, Applicant respectfully submits that new claims are meet the written description provisions of 35 U.S.C. §112, first paragraph.

Rejection of Claims 113-119, 121-123, 132-139, 150, 153 and 156 Under 35 U.S.C. §112, First Paragraph

The Examiner has rejected claims 113-119, 121-123, 132-139, 150, 153 and 156 are rejected under 35 U.S.C. §112, first paragraph, because "the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims." In particular, the Examiner alleges that

> the specification, while being enabling for the specific amino acid sequences and their corresponding nucleotide sequences, vectors, host cells, methods of making a protein and methods of inducing an immune response using polypeptides, does not reasonably provide enablement for any polynucleotide which is homologous

> or a derivative to the recited sequences. The specification is not enabled for amino acid sequences which evidence a percent identity or homology to of the claimed SEQ ID NO 764 which differs from that sequence.

Moreover, the Examiner states

> [h]omologs and derivatives of the instant specification are obtained through the deletion, substitution or insertion of nucleic acids into the polynucleotide sequence which encodes SEQ ID NO 764, the specific locations where these changes can be made so the character of the encoded polypeptide is maintained are not taught.

Claims 121, 122, 136-139, 153 and 156 have been cancelled, thus as applied to these claims the rejection is rendered moot. Furthermore, Applicant respectfully submits that the rejection does not pertain to claims 134 , 135 and 150, as amended. With regard to claims 113-119, 123, 132 and 133, Applicant respectfully traverses the aforementioned rejection.

Claim 113, as amended, is directed to an isolated polypeptide comprising an amino acid sequence that is identical to an amino acid sequence of a naturally occurring *H. pylori* polypeptide which has at least 60% sequence identity with SEQ ID NO:764. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection.

With regard to variants of SEQ ID NO:764 within the scope of the invention, Applicant respectfully maintains that the instant specification meets the enablement requirement of 35 U.S.C. §112, first paragraph. In particular, the specification describes in detail how to construct polypeptide analogs and fragments of the polypeptides of the invention, *e.g.*, using mutagenesis, as well as the testing of such analogs and fragments for activity (see, for example, pages 64-72). In the specific instance of pending claims drawn to polypeptides comprising an epitope recognized by a T cell specific for the polypeptide of SEQ ID NO:764, an antigenic determinant of the polypeptide of SEQ ID NO:764, or polypeptides which are immunologically crossreactive with the polypeptide of SEQ ID NO:764, the specification teaches the use of *in vitro* assays in order to test the immunogenic activity of polypeptides, *e.g.*, the ability of a polypeptide to induce a T cell response (see, for example, pages 60-61).

Yet, the Office Action, at page 14, alleges the specification fails to give adequate direction for the skilled artisan as to predict modifications (*e.g.*, deletions, substitutions, insertions) which would result in a stable, active peptide. Applicant respectfully disagrees and submits that the specification provides guidance in making mutations, including teaching conservative amino acid substitutions that can be introduced while maintaining the biological activity of the polypeptides (see, for example, pages 73-74). In addition, Applicant's specification teaches various modifications that can be used in order to enhance the stability or increase the solubility of polypeptides (see, for example, pages 58-59). With regard to the question as to whether it would require undue experimentation to conduct Applicant's invention as claimed, Applicant asserts that enablement is not precluded by the necessity for some experimentation, and a considerable amount of experimentation is permitted. See, *In re Wands*, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988). Based on the significant guidance provided in the specification, as enumerated and cited above, as well as the generally accepted high level of skill in the art of protein engineering, Applicant submits that one skilled in the art would be able to make and use the claimed polypeptides without undue experimentation.

The Office Action also indicates, at page 14, that the instant specification has failed to provide working examples detailing the construction of a stable polypeptide having percent identity or homology. With regard to the question of the absence of working examples, Applicant asserts that a working example is not required for enablement. See, *Shanks v. Scheffer*, 204 U.S.P.Q. 781, 783 (Pat. Bd. Inter. 1979). Moreover, "there is no magical relation between the number of representative examples and the breadth of the claims". *In re Borkowski and VanVenroy*, 164 U.S.P.Q. 642, 646 (C.C.P.A. 1970). Section §112 only requires that the "specification contain a written description of the invention, and the manner and process of making and using it".

Applicant asserts that all of the presently pending claims are enabled by the specification for the reasons given herein. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

Claim Rejections - 35 U.S.C. §112, Second Paragraph

Rejection of Claims 113-119, 121-123, 132-139, 150, 153 and 156 Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 113-119, 121-123, 132-139, 150, 153, and 156 under 35 U.S.C. §112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." In particular, the Examiner is of the opinion that claims 113-119, 121-123, 132-139, 150, 153 and 156 are indefinite due to the recitation of the phrases "percent sequence identity with SEQ ID No 764" and "is determined by the BLASTP algorithm".

Claims 121, 122, 136-139, 153 and 156 have been cancelled, thus as applied to these claims the rejection is rendered moot. Applicant respectfully submits that claims 113, as amended, does not recite the language "BLASTP", thus obviating the rejection as it pertains to this claim. With regard to claim 113 and claims which depend therefrom, Applicant respectfully traverses this rejection as follows.

Claim 113, as amended, is directed to an isolated polypeptide comprising an amino acid sequence that is identical to an amino acid sequence of a naturally occurring *H. pylori* polypeptide which has at least 60% sequence identity with SEQ ID NO:764. As set forth in new claim 205, sequence identity can be determined by the following algorithm:

(1) aligning the amino acid sequence with SEQ ID NO:764 to identify the number of matching positions shared by the amino acid sequence and SEQ ID NO:764,

(2) dividing the number of matching positions by the total number of amino acids in SEQ ID NO:764, and

(3) multiplying the dividend by 100.

Applicant maintains that claims 113, as amended, and new claim 205 are sufficiently definite in the recitation of the language "percent sequence identity" (see, for example, page 3, lines 29-38 of the instant specification).

In particular, at page 3, lines 29-38, the specification teaches the use of the algorithm (steps (1) through (3) recited in claim 205, as set forth above, to compare two sequences in order to identify matching or "identical" positions shared between the

sequences. Applicant submits that the determination of "sequence identity" as the percentage of residues identical between two aligned sequences is well known in the art, and that the algorithm provided at page 3 of the specification and recited in new claim 205 is art-recognized.

Therefore, one skilled in the art would recognize the metes and bounds of claim 113 and claims which depend therefrom. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the aforementioned rejection.

Rejection of Claims 120-123, 132-135, 149, 152 and 155 Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 120-123, 132-135, 149, 152 and 155 under 35 U.S.C. § 112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." In particular, the Examiner is of the opinion that claims 120-123, 132-135, 149, 152 and 155 are vague and indefinite due to the recitation of the phrase "hybridizes under stringent conditions to the complement of a nucleotide sequence encoding SEQ ID NO 764" since "what the nucleotide sequence is not clear as it can be any nucleotide sequence, of any length, under any type of stringent conditions which will hybridize with SEQ ID No 764." 132-135 149

Claims 121, 122, 152 and 155 have been cancelled, thus as applied to these claims the rejection is rendered moot. In addition, claims 123, 134 and 135, as amended, do not read upon a polypeptide of claim 120 and thus as applied to these claims the rejection is obviated. With regard to claims 120, 132-133 and 149, Applicant respectfully traverses this rejection.

Claim 120, as amended, is directed to an isolated polypeptide comprising an amino acid sequence that is identical to an amino acid sequence of a naturally occurring *H. pylori* polypeptide, the polypeptide ***comprising at least 10 amino acids*** and being encoded by a nucleotide sequence which hybridizes under ***high*** stringency conditions to the complement of a nucleotide sequence encoding SEQ ID NO:764. Claims 132 and 133, as amended, are directed to fusion protein comprising a polypeptide of claim 120

and an additional amino acid sequence. Claim 149 is directed to a composition comprising a polypeptide of claim 120 and a pharmaceutically acceptable carrier.

With regard to the Examiner's assertion that claim 120 is indefinite because the nucleotide sequence can be any sequence, of any length, and will hybridize with SEQ ID NO:764 under any type of stringent conditions, Applicant respectfully submits that amended claim 120 adequately describes the subject matter which Applicant regards as the invention. For example, claim 120, as amended, requires that the nucleotide sequence encode a polypeptide of at least 10 amino acid residues, therefore indicating a length of at least 30 nucleotides. In addition, claim 120 requires that the nucleotide sequence must comprise a base pair composition such that it encodes an amino acid sequence that is identical to that of a naturally occurring *H. pylori*. Moreover, the recited nucleic acid molecules must hybridize with the complement of a nucleotide sequence encoding SEQ ID NO:764 under high stringency conditions.

For at least the aforementioned reasons, Applicant respectfully submits that amended claim 120 and claims which depend therefrom are sufficiently definite under 35 U.S.C. §112, second paragraph. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Rejection of Claims 126-131, 140-148, 154 and 157 Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 126-131, 140-148, 154 and 157 under 35 U.S.C. § 112, second paragraph for lack of clarity due to the recitation of the phrase "at least about". In particular, the Examiner states that "the recitation of this phrase is not defined in the specification and the recitation of this limitation does not distinctly claim applicant's invention."

Claims 126, 140-148, 154 and 157 have been cancelled, thus as applied to these claims the rejection has been rendered moot. With regard to claims 127-131, Applicant respectfully traverses this rejection on the grounds that the term "about" is commonly used claim terminology and is not indefinite under 35 U.S.C. §112, second paragraph. Applicant maintains that the term "about", as used in the pending claims, defines the length of a polypeptide, and that one of ordinary skill in the art would understand what is

claimed in view of the teachings of the specification (see, M.P.E.P. 2173.05). Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

Rejection of Claims 126-131 Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 126-131 under 35 U.S.C. §112, second paragraph, as reciting limitations which lack antecedent basis in claim 125. Claim 126 has been cancelled, thus as applied to this claim the rejection is rendered moot. With regard to claims 127-131, Applicant respectfully disagrees and traverses this rejection.

Claim 125, as amended, is directed to an isolated polypeptide comprising ***at least*** 10 consecutive amino acid residues of SEQ ID NO:764. Amended claims 127-131 depend from and further limit claim 125 by specifying that the isolated polypeptide comprises ***at least about*** 12, 16, 20, 50 and 100 consecutive amino acid residues, respectively, of SEQ ID NO:764. The length of the polypeptide in each of amended claims 127-131 meets the requirements of claim 125 from which it depends in that polypeptides comprising at least 12, 16, 20, 50 and 100 amino acid residues also comprise at least 5 consecutive amino acids of SEQ ID NO:764. Therefore, Applicant respectfully submits that amended claims 127-131 are in proper dependent form, and respectfully request that this objection be reconsidered and withdrawn.

Rejection of Claims 132-140 Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 132-140 under 35 U.S.C. § 112, second paragraph as being vague and indefinite due to the recitation of the phrase "an isolated polypeptide". In particular, the Examiner argues that "the claimed invention is a fusion protein operably linked to an additional amino acid sequence," and that "it is not clear how an isolated polypeptide, isolated from natural sources is also a fusion protein."

Claims 136-140 have been cancelled, thus as applied to these claims the rejection is rendered moot. With regard to claims 132-135, Applicant respectfully traverses on the grounds that the aforementioned rejection does not apply to these claims as amended.

Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

Rejection of Claims 152-157 Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 152- 157 under 35 U.S.C. § 112, second paragraph, as vague and indefinite due to the recitation of the phrase "an effective amount". The Examiner alleges that "the amount is not clear as what the amount is effective for is not defined in the claims.

Claims 152-157 have been cancelled, thus as applied to these claims the rejection is rendered moot.

Rejection of Claims 142-148 Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 142-148 under 35 U.S.C. § 112, second paragraph, as "the meets and bounds of the claim can not be determined." In particular, the Examiner states

> [c]laims 142-148 recite compositions which comprise immunogenic polypeptides wherein at least one of the polypeptides comprises at least about 10 consecutive amino acids of SEQ ID NO 764. What other immunogenic polypeptides are contained in the compositions is not distinctly claimed.

Claims 142-148 have been cancelled, thus as applied to these claims the rejection is rendered moot.

Claim Rejections - 35 U.S.C §102

Rejection of Claims 125 and 140 Under 35 U.S.C. §102(e) as Anticipated by Wang or Duncan

The Examiner has rejected claims 125 and 140 are rejected under 35 U.S.C. §102(e) as being anticipated by Wang (US Pat. 5, 476, 765) or Duncan (EP-371818A).

In particular, the Examiner characterizes the Wang and Duncan patent publications as follows

> Wang and Duncan (EP-371818A) disclose an immunogenic polypeptide which share 100% identity with 6 amino acids of SEQ ID No 764 for the diagnosis of HIV infection, which is biotinylated (Wang) (an additional amino acid sequence) wherein the disclosed immunogenic polypeptide comprises 16 and 20 amino acids, respectively and therefore anticipates the now claimed invention.

Claim 140 has been cancelled, thus as applied to this claim the rejection is rendered moot. Applicant respectfully submits that this rejection does not apply to claim 125 as amended for at least the following reasons.

For a prior art reference to anticipate a claimed invention in terms of 35 USC § 102, the prior art must teach ***each and every element*** of the claimed invention. Lewmar Marine v. Barient, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987).

Claim 125, as amended, is directed to an isolated polypeptide comprising ***at least 10*** consecutive amino acid residues of SEQ ID NO:764.

Wang (U.S. Patent No. 5,476,765) discloses peptides having amino acid sequences corresponding to transmembrane and external segments of the envelope glycoprotein of HTLV-I/HTLV-II. Duncan (EP-371818A) discloses peptides capable of binding to antibodies specific for HIV-2. The peptides of Wang and Duncan include 6 consecutive amino acid residues of SEQ ID NO:764 within a longer amino acid sequence.

Wang and Duncan do not teach or suggest an isolated polypeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO:764, or a fusion protein comprising a polypeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO:764 and an additional amino acid sequence. Therefore, Wang and Duncan do not teach each and every element of claim 125, as is required for anticipation. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Rejection of Claims 125 and 140 Under 35 U.S.C. §102(e) as Anticipated by Kjeldsen et al.

The Examiner has also rejected claims 125 and 140 under 35 U.S.C. §102(e) as being anticipated by Kjeldsen *et al.* In particular , the Examiner states

> Kjeldsen *et al.* disclose an immunogenic polypeptide which share 100% identity with 6 amino acids of SEQ ID No 764 wherein the disclosed immunogenic polypeptide comprises 935 amino acids, and therefore comprises an additional amino acid sequence. The reference anticipates the now claimed invention.

Claim 140 has been cancelled, thus as applied to this claim the rejection is rendered moot. With regard to claim 125 as amended, Applicant respectfully traverses this rejection.

Claim 125, as amended, is directed to an isolated polypeptide comprising ***at least 10*** consecutive amino acid residues of SEQ ID NO:764.

Kjeldsen *et al.* (WO 95/34666) discloses synthetic leader peptide sequences for secreting polypeptides in yeast which include 6 consecutive amino acids of SEQ ID NO:764 within a larger amino acid sequence. As Kjeldsen *et al.* does not teach or suggest an isolated polypeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO:764, or a fusion protein comprising a polypeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO:764 and an additional amino acid sequence, it does not teach each and every element of claim 125 as is required for anticipation.

Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

Rejection of Claims 125, 126 and 140 Under 35 U.S.C. §102(a) as Anticipated by Davies et al.

The Examiner has rejected claims 125, 126 and 140 under 35 U.S.C. §102(a) as being anticipated by Davies *et al* (WO 94/10288). In particular, the Examiner alleges

> Davies *et al.* disclose a nucleotide sequence which encodes a recombinant and isolated polypeptide which share 100% identity with 5 amino acids of SEQ ID No 764 and about at least 10 amino acids of SEQ ID No 764, wherein 8 is at least about 10 which was expressed as a fusion protein and therefore anticipates the now claimed invention.

Claims 126 and 140 have been cancelled, thus as applied to these claims the rejection is rendered moot. With regard to claim 125 as amended, Applicant respectfully traverses this rejection.

Claim 125, as amended, is directed to an isolated polypeptide comprising ***at least 10*** consecutive amino acid residues of SEQ ID NO:764.

Davies *et al.* (WO 94/10288) teaches nucleic acid sequences encoding plant acyl-ACP thioesterases. The cDNA clone CMT10 contains a sequence of 24 nucleotides that, if translated in the reverse orientation, encodes 8 consecutive amino acids of SEQ ID NO:764. Davies *et al.* does not translate, in the reverse orientation, the sequence of 24 nucleotides suggested by the Examiner. Thus, no amino acid sequence corresponding to SEQ ID NO:764 is described by Davies *et al.*

Accordingly, Davies *et al.* does not teach or suggest an isolated polypeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO:764, or a fusion protein comprising a polypeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO:764 and an additional amino acid sequence. As such, Davies *et al.* fails to teach each and every element of claim 125, and therefore does not anticipate this claim. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this §102(a) rejection.

Rejection of Claims 125, 126 and 140 Under 35 U.S.C. §102(a) as Anticipated by Crowe et al.

The Examiner has also rejected claims 125, 126 and 140 under 35 U.S.C. §102(a) as being anticipated by Crowe *et al* (WO 94/25596). In particular, the Examiner states

> Crowe *et al* disclose a nucleotide sequence which encodes a recombinant and isolated polypeptide which share 100% identity with 5 amino acids of SEQ ID No 764 and about at least 10 amino acids of SEQ ID No 764, wherein 8 is at least about 10 and therefore anticipates the now claimed invention.

Claims 126 and 140 have been cancelled, thus as applied to these claims the rejection is rendered moot. With regard to claim 125 as amended, Applicant respectfully traverses this rejection.

Claim 125, as amended, is directed to an isolated polypeptide comprising ***at least 10*** consecutive amino acid residues of SEQ ID NO:764.

Crowe *et al.* (WO 94/25596) discloses OspC antigen vaccines for the prevention and treatment of Lyme disease. The spirochete OspC antigens disclosed by Crowe *et al.* contain 8 consecutive amino acids of SEQ ID NO:764 within a larger amino acid sequence. As Crowe *et al.* does not teach or suggest an isolated polypeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO:764, or a fusion protein comprising a polypeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO:764 and an additional amino acid sequence, it does not teach each and every element of claim 125 as is required for anticipation.

Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

Rejection of Claims 125 and 140 Under 35 U.S.C. §102(b) as Anticipated by Fahnestock

The Examiner has rejected claims 125 and 140 under 35 U.S.C. §102(b) as being anticipated by Fahnestock (WO88/10306). In particular, the Examiner characterizes the Fahnestock patent publication as follows

> Fahnestock (WO88/10306) disclose a nucleotide sequence which encodes a recombinant and isolated polypeptide which share 100% identity with 5 amino acids of SEQ ID No 764 and therefore anticipates the now claimed invention.

Claim 140 has been cancelled, thus as applied to this claim the rejection is rendered moot. With regard to claim 125 as amended, Applicant respectfully traverses this rejection.

Claim 125, as amended, is directed to an isolated polypeptide comprising ***at least 10*** consecutive amino acid residues of SEQ ID NO:764.

Fahnestock (WO88/10306) discloses genes encoding *Streptococcus* protein G variants. The protein G gene of Fahnestock contains a nucleic acid sequence of 21 nucleotides that, if translated in the reverse orientation, encodes 7 consecutive amino acids of SEQ ID NO:764. Fahnestock does not translate, in the reverse orientation, these 21nucleotides as suggested by the Examiner.

Accordingly, Fahnestock does not teach or suggest an isolated polypeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO:764, or a fusion protein comprising a polypeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO:764 and an additional amino acid sequence. Therefore, Fahnestock does not anticipate claim 125, as it does not teach each and every element of this claim. Therefore, Applicant respectfully requests reconsideration and withdrawal of this §102(b) rejection.

Rejection of Claims 125, 126 and 140 Under 35 U.S.C. §102(b) as Anticipated by Fuchs et al.

The Examiner has rejected claims 125, 126 and 140 under 35 U.S.C. §102(b) as being anticipated by Fuchs *et al.* (WO 91/09870). In particular, the Examiner alleges

> Fuchs *et al.* disclose a nucleotide sequence which encodes a recombinant and isolated polypeptide which share 100% identity with 5 amino acids of SEQ ID No. 764 and about at least 10 amino acids of SEQ ID 764, wherein 8 is at least about 10 and therefore anticipates the now claimed invention.

Claims 126 and 140 have been cancelled, thus as applied to these claims the rejection is rendered moot. With regard to claim 125 as amended, Applicant respectfully traverses this rejection.

Claim 125, as amended, is directed to an isolated polypeptide comprising ***at least 10*** consecutive amino acid residues of SEQ ID NO:764.

Fuchs *et al.* (WO 91/09870) teaches immunologically active proteins from *Borrelia Burgdorferi* which contain 8 consecutive amino acids of SEQ ID NO:764 within a larger amino acid sequence. Since Fuchs *et al.* does not teach or suggest an isolated polypeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO:764, or a fusion protein comprising a polypeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO:764 and an additional amino acid sequence, it fails to teach each and every element of claim 125, as is required for anticipation.

Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

Rejection of Claims 125, 126 and 140 Under 35 U.S.C. §102(b) as Anticipated by Alexos et al.

The Examiner has rejected claims 125, 126 and 140 under 35 U.S.C. §102 (b) as being anticipated by Axelos *et al.* (1989). In particular, the Examiner states

> Axelos *et al* disclose a nucleotide sequence which encodes a recombinant and isolated polypeptide which share 100 % identity with 9 amino acids of SEQ ID No. 764. The disclosed immunogenic polypeptide comprises additional amino acid and therefore meets the claim limitations of claim 140. Axelos *et al* anticipates the now claimed invention.

Claims 126 and 140 have been cancelled, thus as applied to these claims the rejection is rendered moot. With regard to claim 125 as amended, Applicant respectfully traverses this rejection.

Claim 125, as amended, is directed to an isolated polypeptide comprising ***at least 10*** consecutive amino acid residues of SEQ ID NO:764.

Alexos *et al.* discloses the gene encoding Arabidopsis thaliana translation elongation factor EF-1α. The EF-1α gene disclosed in Alexos *et al.* contains a nucleic acid sequence of 27 nucleotides that, when translated in the reverse orientation, encodes 9 consecutive amino acids of SEQ ID NO:764. Alexos *et al.* does not translate in the reverse orientation these 27 nucleotides as suggested by the Examiner.

Accordingly, Alexos *et al.* does not teach or suggest an isolated polypeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO:764, or a fusion protein comprising a polypeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO:764 and an additional amino acid sequence. Therefore, Alexos *et al.* does not anticipate claim 125, as it does not teach each and every element of this claim. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this §102(b) rejection.

Rejection of Claims 120-123, 132-135, 149, 152 and 155 Under 35 U.S.C. §102(b) as Anticipated by Newman et al.

The Examiner has rejected claims 120-123, 132-135, 149, 152 and 155 under 35 U.S.C. §102(b) as being anticipated by Newman *et al.* (1994). The Examiner characterizes the Newman *et al.* reference as follows

> Newman *et al* disclose a nucleotide sequence which encodes an isolated or purified recombinant polypeptide wherein the nucleic acid sequence share 76.923 sequence similarity and would hybridize under stringent conditions to SEQ ID No 764 and therefore anticipates the now claimed polypeptide.

Claims 121, 122, 152 and 155 have been cancelled, thus as applied to these claims the rejection is rendered moot. Moreover, Applicant respectfully submits that this rejection does not apply to claims 123, 134 and 135 as amended. With regard to claims 120, 132, 133 and 149, Applicant respectfully traverses this rejection as follows.

For a prior art reference to anticipate a claimed invention in terms of 35 USC § 102, the prior art must teach ***each and every element*** of the claimed invention. Lewmar Marine v. Barient, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987).

Claim 120 is directed to an isolated polypeptide comprising an amino acid sequence that is identical to an amino acid sequence of a naturally occurring *H. pylori* polypeptide, the polypeptide comprising at least 10 amino acid residues and being encoded by a nucleotide sequence that hybridizes under highly stringent conditions to the complement of a nucleotide sequence encoding SEQ ID NO:764. Claims 132 and 133 are directed to a fusion protein comprising a polypeptide of claim 120 and an additional amino acid sequence. Claim 149 is drawn to a composition comprising a polypeptide of claim 120.

Newman *et al.* disclose the partial sequencing of anonymous Arabidopsis cDNA clones. The Examiner has cited a 75 base pair nucleic acid fragment within a cDNA clone of Newman *et al.* that, when translated in the reverse orientation from the complementary strand, encodes a ***polypeptide*** that is 42.3% identical and 76.9% similar to a polypeptide fragment of SEQ ID NO:764. Newman *et al.* does not translate in the reverse orientation the 75 nucleotides as suggested by the Examiner.

Thus, Applicant respectfully submits that the cDNA of Newman *et al.* fails to teach or suggest an isolated polypeptide comprising an amino acid sequence that is identical to an amino acid sequence of a naturally occurring *H. pylori* polypeptide, as is required by claim 120. In addition, Applicant respectfully submits that it is unknown whether the cDNA fragment of Newman *et al.* would hybridize to the complement of a nucleotide sequence encoding SEQ ID NO:764 under high stringency conditions, as the sequence alignment provided by the Examiner does not allow a quantitative assessment of the degree of nucleotide sequence similarity between the nucleotide sequence of Newman *et al.* and the complement of the nucleotide sequence encoding SEQ ID NO:764.

In light of the foregoing, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Rejection of Claims 142-148 Under 35 U.S.C. §102(e) as Anticipated by Czinn et al.

The Examiner has rejected claims 142-148 under 35 U.S.C. §102(e) as being anticipated by Czinn *et al.* (U.S. Patent No. 5,538,729). In particular, the Examiner characterizes the Czinn *et al.* reference as follows

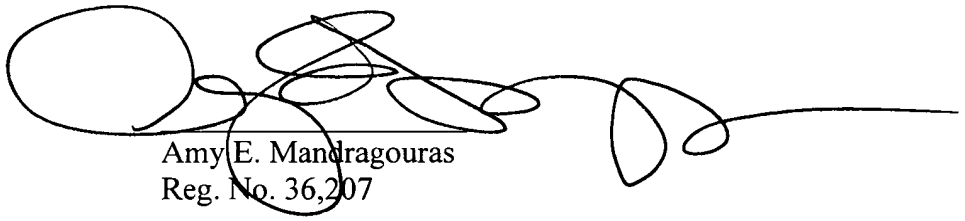
> Czinn *et al* disclose compositions comprising immunogenic polypeptides from Helicobacter and teach a method of oral immunization against *Helicobacter pylori* and a vaccine comprising Helicobacter polypeptides and an adjuvant, wherein the adjuvant is a mucosal adjuvant. The compositions evidenced a significantly enhanced immune response when a mucosal adjuvant, specifically cholera toxin, was used with the vaccine comprising Helicobacter. The compositions comprising isolated immunogenic polypeptides of Czinn would inherently comprise the instantly claimed polypeptide as the composition of Czinn comprised all the antigens present in a whole cell lysate of Helicobacter.

Claims 142-148 have been cancelled, thus as applied to these claims the rejection is rendered moot.

CONCLUSION

In view of the foregoing amendments and remarks, reconsideration of the rejections and allowance of all pending claims are respectfully requested. If a telephone conversation with Applicant's Attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7400.

Respectfully submitted,



Amy E. Mandragouras
Reg. No. 36,207

LAHIVE & COCKFIELD, LLP
28 State Street
Boston, MA 02109
(617) 227-7400
Dated: January 31, 2000

APPENDIX A

113. An isolated polypeptide comprising an amino acid sequence that is identical to an amino acid sequence of a naturally occurring *H. pylori* polypeptide, wherein said isolated polypeptide has at least 60 percent sequence identity with SEQ ID NO: 764.

114. The isolated polypeptide of claim 113 comprising an amino acid sequence having at least 70 percent sequence identity with SEQ ID NO: 764.

115. The isolated polypeptide of claim 113 comprising an amino acid sequence having at least 80 percent sequence identity with SEQ ID NO: 764.

116. The isolated polypeptide of claim 113 comprising an amino acid sequence having at least 90 percent sequence identity with SEQ ID NO: 764.

117. The isolated polypeptide of claim 113 comprising an amino acid sequence having at least 95 percent sequence identity with SEQ ID NO: 764.

118. The isolated polypeptide of claim 113 comprising an amino acid sequence having at least 98 percent sequence identity with SEQ ID NO: 764.

119. The isolated polypeptide of claim 113 comprising an amino acid sequence having at least 99 percent sequence identity with SEQ ID NO: 764.

120. An isolated polypeptide comprising an amino acid sequence that is identical to an amino acid sequence of a naturally occurring *H. pylori* polypeptide, wherein said isolated polypeptide comprises at least 10 amino acid residues and is encoded by a nucleotide sequence which hybridizes under high stringency conditions to the complement of a nucleotide sequence encoding SEQ ID NO: 764.

123. An isolated polypeptide of any one of claims 196-204 which is a recombinant polypeptide.

124. An isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 764.

125. An isolated polypeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO: 764.

127. The isolated polypeptide of claim 125 comprising at least about 12 consecutive amino acid residues of SEQ ID NO: 764.

128. The isolated polypeptide of claim 125 comprising at least about 16 consecutive amino acid residues of SEQ ID NO: 764.

129. The isolated polypeptide of claim 125 comprising at least about 20 consecutive amino acid residues of SEQ ID NO: 764.

130. The isolated polypeptide of claim 125 comprising at least about 50 consecutive amino acid residues of SEQ ID NO: 764.

131. The isolated polypeptide of claim 125 comprising at least about 100 consecutive amino acid residues of SEQ ID NO: 764.

132. A fusion protein comprising a polypeptide of any one of claims 113, 120 or 196-204 and an additional amino acid sequence.

133. The fusion protein of claim 132, wherein the additional amino acid sequence comprises an *H. pylori* polypeptide.

134. A fusion protein comprising a polypeptide of claim 125 and an additional amino acid sequence.

135. The fusion protein of claim 134, wherein the additional amino acid sequence comprises an *H. pylori* polypeptide.

149. A composition comprising a polypeptide of any one of claims 113, 120 or 196-204 and a pharmaceutically acceptable carrier.

150. A composition comprising a polypeptide of claim 125 and a pharmaceutically acceptable carrier.

196. An isolated polypeptide comprising at least one epitope recognized by a T cell receptor specific for the polypeptide set forth in SEQ ID NO:764, said isolated polypeptide comprising an amino acid sequence having at least 60 percent sequence identity with SEQ ID NO: 764.

197. An isolated polypeptide comprising at least one antigenic determinant of the polypeptide set forth in SEQ ID NO:764, said isolated polypeptide comprising an amino acid sequence having at least 60 percent sequence identity with SEQ ID NO: 764.

198. An isolated polypeptide that is immunologically crossreactive with the polypeptide set forth in SEQ ID NO:764, said isolated polypeptide comprising an amino acid sequence having at least 60 percent sequence identity with SEQ ID NO: 764.

199. An isolated polypeptide comprising at least one epitope recognized by a T cell receptor specific for the polypeptide set forth in SEQ ID NO:764, wherein said isolated polypeptide comprises at least 10 amino acid residues and is encoded by a nucleotide sequence which hybridizes under high stringency conditions to the complement of a nucleotide sequence encoding SEQ ID NO:764.

200. An isolated polypeptide comprising at least one antigenic determinant of the polypeptide set forth in SEQ ID NO:764, wherein said isolated polypeptide comprises at least 10 amino acid residues and is encoded by a nucleotide sequence which hybridizes under high stringency conditions to the complement of a nucleotide sequence encoding SEQ ID NO:764.

201. An isolated polypeptide that is immunologically crossreactive with the polypeptide set forth in SEQ ID NO:764, wherein said isolated polypeptide comprises at least 10 amino acid residues and is encoded by a nucleotide sequence which hybridizes under high stringency conditions to the complement of a nucleotide sequence encoding SEQ ID NO:764.

202. An isolated polypeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO: 764, wherein said polypeptide comprises at least one epitope recognized by a T cell receptor specific for the polypeptide set forth in SEQ ID NO:764.

203. An isolated polypeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO: 764, wherein said polypeptide comprises at least one antigenic determinant of the polypeptide set forth in SEQ ID NO:764.

204. An isolated polypeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO: 764, wherein said polypeptide is immunologically crossreactive with the polypeptide set forth in SEQ ID NO:764.

205. The isolated polypeptide of any one of claims 113 or 196-198 wherein said sequence identity with SEQ ID NO:764 is determined by

(1) aligning the amino acid sequence with SEQ ID NO:764 to identify the number of matching positions shared by the amino acid sequence and SEQ ID NO:764,

(2) dividing the number of matching positions by the total number of amino acids in SEQ ID NO:764, and

(3) multiplying the dividend by 100.

206. The isolated polypeptide of any one of claims 113 or 196-198 comprising at least 10 amino acid residues.

207. The isolated polypeptide of any one of claims 113, 120 or 196-204 comprising at least about 12 amino acid residues.

208. The isolated polypeptide of any one of claims 113, 120 or 196-204 comprising at least about 16 amino acid residues.

209. The isolated polypeptide of any one of claims 113, 120 or 196-204 comprising at least about 20 amino acid residues.

210. The isolated polypeptide of any one of claims 113, 120 or 196-204 comprising at least about 50 amino acid residues.

211. The isolated polypeptide of any one of claims 113, 120 or 196-204 comprising at least about 100 amino acid residues.

212. A composition comprising a fusion protein of claim 132 and a pharmaceutically acceptable carrier.

213. A composition comprising a fusion protein of claim 134 and a pharmaceutically acceptable carrier.